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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/991,143	12/16/1997	BIANCA M. CONTI-FINE	600.423US1	2148

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EXAMINER	
NOLAN, PATRICK J	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/991,143	CONTI-FINE, BIANCA M.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,13,17,18,31,34-39 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42* is/are allowed.

6)☒ Claim(s) *1-3,5,7,13,17,18,31,34-39 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Part III DETAILED ACTION

1. Claims 1-3, 5, 7, 13, 16-18, 31, 34-39, 41-44 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-6-03 has been entered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 2, 13, 31 34 and 37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,106,844, of record, for reasons set forth in Paper No. 34. (B).

Applicant's arguments filed 4-30-03 have been fully considered but are not found persuasive.

Applicant argues that just because the universal epitope was found for mice it is uncertain whether the same peptide has a universal epitope for humans.

The '844 patent teaches how to find said universal epitopes in humans, such a teaching that was equivalent to applicant's specification for determining universal immunodominant sequences in yet undetermined antigen sequences. The burden on a prior art reference to be enabled is that it teaches one of skill in the art how to make and use, actual reduction to practice is not required.

Applicant argues the peptides were not recognized by all five strains of mice's spleen cells, this is not a requirement of immunodominant or universal as defined by Applicant's specification.

Applicant argues that King does not prived any data relating to the impact of of the administration of the peptides on antibody production and that T cell epitope administration does

not necessarily result in decrease in aberrant, pathogenic or undesirable antibody production. Applicant's own specification teaches selecting immunodominant T cell epitopes for therapy administration and the '844 patent teaches that the peptides decrease the allergic response and minimize the IgE response.

Lastly, Applicant argue it was unknown prior to Applicant's disclosure, whether not antigen or peptide administration would be efficacious. Applicant has provided no direct evidence that the teachings of the '844 patent fail to provide one of skill in the art how to make and use the peptides.

5. Claims 2, 13, 31, 34 and 37-39 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,268,491 (A).

The '491 patent teaches administering T cell epitopes from fungal allergens, via inhalation, to treat humans, wherein said peptides reduce IgE levels, are immunodominant and universal, and anergize CD4+ T cells. The '491 patent further teaches administering a T cell blocking agent, B7, that would inhibit the ability of the B cell to proliferate in response to stimulating the T-helper cell.

The prior art teachings anticipate the claimed invention.

6. Claims 1-3, 5, 7, 13, 17, 31, 34-38, 41 and 44 rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,268,491 (B).

Te '308 patent teaches administering IgG-peptide complexes orally, to tolerize patients by decreasing antibody responses to Factor VIII or to acetylcholine receptors or to dust mite allergens, wherein said peptide comprises the immunodominant part of the full length antigen (see column 10 in particular).

The prior art teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3, 5, 17, 18, 31, 34-36 and 41 are rejected under 35 U.S.C. § 103 as being unpatentable over Daniel et al. (U), of record for reasons set forth in Paper No.34.

Applicant argues that because IDDM is not an antibody mediated disease there would be not motivation to treat humans.

Daniel et al., specifically discloses "overt diabetes is often preceded by the appearance of circulating antibodies specific to a number of beta cell products, amongst which is insulin". In addition if IDDM is not an antibody mediated disease why is Applicant claiming insulin in the claim set? What disease are they treating with insulin, if not IDDM?

Applicant argues that Daniel et al., question insulin based therapies of previous reports. However, those reports were on full length insulin therapies. Daniel et al., teaches that the NOD mouse which develops IDDM with many similarities to the human disease, is considered a good model of Type I diabetes.

8. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The word mammal has no antecedent basis in claim 42.

9. Claim 42 in its present form is deemed allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 to 4:30.

11. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 872-9306.

Pat J Nol

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
8/20/03